PHYSICIAN'S OPERATION MANUAL

KING OF HEARTS

EXPRESS® AF

CARDIAC EVENT RECORDER

Instromedix®
A Card Guard® Company
SAN DIEGO, CA 92121 USA

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Note: *Operation of this device near sources of electromagnetic interference (such as radio transmitters) may adversely affect the quality of the recorded ECG signal. This device complies with AAMI EC38–94 applicable specifications regarding electro-magnetic compatibility.*

In the USA contact:
Instromedix®
A Card Guard Company
6779 Mesa Ridge Road, Suite 200
San Diego, California 92121-2996
(858) 777-2200
(800) 633-3361
Fax: (858) 777-2373
www.instromedix.com

European Authorized Representative:
Obelis s.a.
34, Av.de Tervuren, bte 44
B-1040 Brussels, Belgium
Tel: (32)2.732.59.54
Fax: (32)2.732.60.03
Email: mail@obelis.net

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INTRODUCTION

The **King of Hearts Express® AF** recorder is a patient-activated recorder designed for diagnostic evaluation of transient symptoms; such as dizziness, palpitations and syncope. The recorder provides single lead ECG morphology which may be used to visualize arrhythmias. It also provides automatic recording for detected bradycardia, tachycardia or atrial fibrillation rhythms.

The following chart highlights the key features of the **King of Hearts Express® AF** recorder:

	King of Hearts Express AF Recorder
Total Memory	10 minutes
Factory Default Pre/Post (sec)	45/15
Number of Events	Up to 60
Programmable	Yes
LCD Display	Yes
Automatic HR Trigger	Yes
Automatic AF Trigger	Yes
Accelerated Transmission	Yes

Using looping memory, the **King of Hearts Express® AF** recorder captures ECG data, both before and after the patient experiences a cardiac symptom and the recording is activated. The patient wears the **King of Hearts Express® AF** recorder day and night while it continuously scans ECG activity. Upon activation, a cardiac event is recorded and stored in solid-state memory.

With a sampling rate of 218 measurements per second, the recorder produces good amplitude and resolution with the very fast QRS complexes seen in some pediatric patients.

Used in conjunction with a compatible telephonic ECG receiver or a receiving service, the **King of Hearts Express® AF** recorder provides a practical and convenient method for collecting diagnostic ECGs over an extended period of time for patients with symptoms suggesting a cardiac arrhythmia.

The **King of Hearts Express® AF** recorder has a built-in LCD display that enables you to easily control a variety of functions, so that the operation of the recorder is tailored to the needs of the patient and the clinician.

> ***Note:*** *Although pacemaker spikes are sometimes visible on the ECG recordings, this recorder has no special provision for pacer spike detection or display.*

WARNING: Do not use the **King of Hearts Express® AF** recorder in combination with an external cardiac defibrillator or high frequency surgical equipment. Disconnect the patient leads from the electrodes prior to performing external defibrillation or using electrosurgical equipment. There are no known safety hazards due to the use and operation of a cardiac pacemaker or other electrical cardiac stimulator with the **King of Hearts Express® AF** recorder.

FEATURES

Easy to Use

The **King of Hearts Express AF** recorder is designed to be both comfortable and easy to use for cardiac patients needing long-term ambulatory monitoring. The recorder may be clipped to a belt, slipped into a shirt pocket, or worn around the neck like a pendant.

The small, portable **King of Hearts Express AF** recorder is worn with two electrodes. When the patient feels a symptom, a simple press of a button records and stores the ECG surrounding the event.

Following your defined protocol, the patient sends the stored data to a telephonic ECG receiver in your office or to a receiving service. The patient may bring the recorder directly to your office for ECG download, diagnosis and follow-up.

The recorder is programmable and is easily identified by the presence of an LCD display.

The **King of Hearts Express AF** recorder can also transmit ECG data using the high speed Accelerated Transmission Protocol™ (ATP™) method. Facilities equipped with a LifeSigns® Receiving Center 2000 (LRC™ 2000) receiver, or a similar ATP method compatible receiver, may activate ATP feature (mode) and receive data at three times the normal rate.

The **King of Hearts Express AF** recorder may be programmed to automatically record an ECG when the heart rate rises above a preset tachycardia value or falls below a preset bradycardia value. The physician may adjust these settings in the automatic rate-trigger feature.

It may also be programmed to automatically record an ECG when the device detects an atrial fibrillation condition.

The recorder can alert the user when an autotrigger recording is made.

Easy to Maintain

A fresh set of AAA alkaline batteries typically powers the **King of Hearts Express AF** recorder for seven days. Additionally, the memory is protected by an internal lithium battery.

Flexible Programming

You may program the **King of Hearts Express AF** recorder to fit the patient's condition and your own preferences, as follows:

- Define the time frame for which the ECG is captured and stored in memory by setting the **bE**fore-event and **AF**ter-event storage times. This determines the total number of events that may be recorded before the memory is full.
- Limit the maximum number of recorded events to fewer than the recorder's capacity.
- Program the **SP**eaker to remain **On** or **OFF** during recording.
- Program the heart rate display **On** or **OFF**.
- Program the automatic triggers **On** or **OFF**.
- Set minimum heart rate for tachycardia detection when automatic rate trigger is on.
- Set maximum heart rate for bradycardia detection when automatic trigger is on.
- Set maximum number of events which may be recorded using the automatic rate trigger.
- Program the accelerated transmission function **On** or **OFF**.
- Program the recorder to transmit the recorder **Id**entification number.
- Program the autorecorded event alert **On** or **OFF**.
- Restore default values using Quick Program settings.

PHYSICAL FEATURES

On the Recorder

- Two control buttons:

  Send
  Record

- An internal speaker for telephonic data transmission.
- A clip for attaching the recorder to a belt or to garments.
- The status message display window. The status message may take the following forms:

Numerals representing heart rate, battery life, and/or number of events available to record.

An alphabetic feature identifier (such as, **bE**).

Symbols describing current recorder status:

low battery

memory full

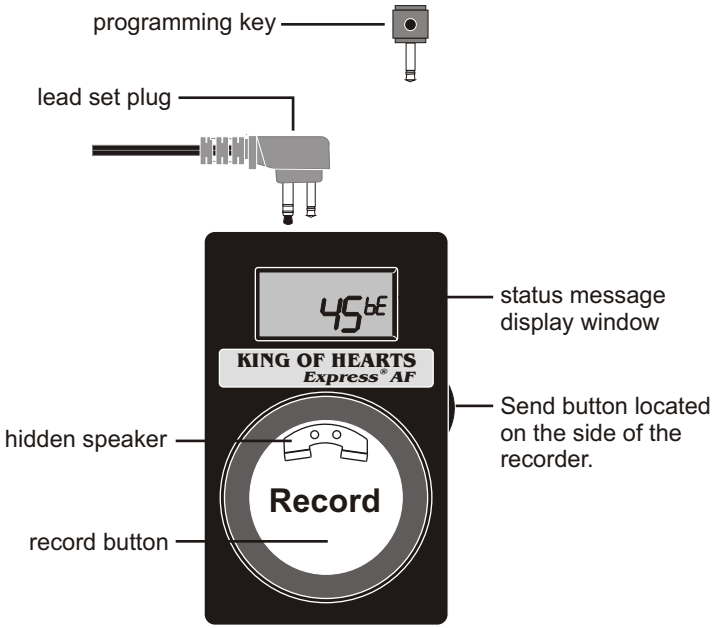
scanning/recording

transmitting

Separate Items

- A two electrode single channel lead set is included with the **King of Hearts Express AF** recorder. The lead set plugs into the lead set jack on the top end of the recorder.
- A programming key. When inserted into the programming jack on the top end of the recorder, this key enables access to the programming mode.
- A lanyard (cord), which may be used to wear the recorder around the neck. A belt clip, storage case and batteries are also included.

KING OF HEARTS EXPRESS AF
CARDIAC EVENT RECORDER



OPERATION

The following describes the essential elements of patient hookup and the operation of the **King of Hearts Express AF** cardiac event recorder. If you have questions, please call Instromedix® at 1-800-237-4500.

> ***Note:*** *It is recommended that the* ***King of Hearts Express AF*** *recorder be demonstrated and a baseline recording taken on each patient for proper operation and to verify the lead wire connections.*

PATIENT HOOKUP

Electrodes

Good electrical contact between the electrodes, lead set and the skin is essential for a high quality ECG signal. Electrodes designed for long-term monitoring are recommended (similar to those used in a Holter procedure).

> ***Note:*** *Instromedix® recommends the use of low impedance Holter electrodes; such as, Lead-Lok® Pre-Gelled Electrodes. Typically, these will need to be changed every 3-4 days. If an electrode becomes loose, it should be replaced immediately with a new electrode.*

> ***Note:*** *Use only the lead set supplied with the* ***King of Hearts Express AF*** *recorder or its direct replacement lead set.*

Determine Electrode Placement

Any standard lead configuration may be used with the **King of Hearts Express AF** recorder. The diagram on Page 9 shows an electrode placement that typically achieves good results; however, optimum electrode placement varies according to patient body shape, size and the desired view of ECG.

Site Preparation and the Position for Electrode Placement

- The skin surface should be cleansed with alcohol, allowed to dry, and abraded according to standard Holter or stress-testing methods (as needed).
- The adhesive electrodes may be worn in the shower or bath but they should not get soaked. The skin around the electrodes should be gently washed and the electrodes repressed to the skin after drying.
- Any electrode which loosens during the monitoring period must be replaced.
- Electrodes having dried gel should not be used.
- When reattaching the lead wires to the electrodes, connect the lead wires and then secure them with service loops.
- Perform an electrical confidence check to verify good electrical contact.

Apply Electrodes

- Remove an electrode from its sealed package and peel off the protective back cover.
- Discard any electrode having dry gel.
- Press the electrode firmly onto the prepared site. Replace any electrode which does not adhere securely.

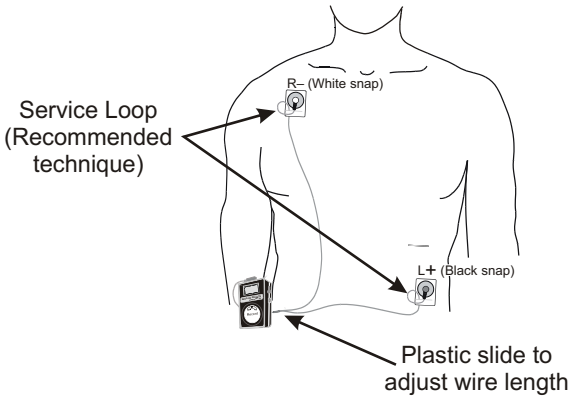
Connect Lead Wires

- Snap the lead wires onto the electrodes: white snap on the patient's right, black snap on the patient's left.
- Make sure the electrode/lead wire connections are properly stabilized to prevent movement. Use a "service loop" below the electrode/lead wire snap to provide strain relief.
- Lead wire lengths may be adjusted by moistening the clear plastic slide and gently moving it, taking care not to stretch the lead wires.

Note: *Instromedix® recommends that an electrical confidence check be performed each time electrodes are connected.* *See Page 33.*

Note: *Conductive parts of the electrodes and associated connectors for this recorder, should not contact other conductive parts, including earth.*

ELECTRODE PLACEMENT



ACTIVATE SCANNING MODE

After the electrodes are connected to the lead wires, insert the lead set plug into the jack on the top end of the **King of Hearts Express AF** recorder.

The recorder will beep once, then again about 5 seconds later.

After a pause lasting up to 75 seconds, you will hear a distinctive double beep, which signals that the **King of Hearts Express AF** recorder has completed a start-up check and is scanning the ECG activity. The recorder does not scan during the start-up check.

Note: *If instead of a double beep you hear five beeps, it means that the memory is full. The patient should remove the lead wire plug and transmit as soon as possible. If you wish to discard the signals without transmitting, press the* ***Send*** *button and allow the signals to play completely through (not recommended).*

If the heart rate display (rd) has been programmed **On**, the heart rate should appear within 20 seconds after start-up and remain on the display during scanning. This verifies that the **King of Hearts Express AF** recorder is functioning properly and that it is receiving the ECG data.

Status Message Display During Start-Up

During the start-up check the status window displays two numbers and/or letters.

The number of events available to be recorded with the current programmed settings.

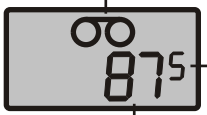
The estimated number of days of battery life remaining.

Note: *An F will appear in the status window rather than a number when the memory is full.*

Note: *An additional low battery indicator is provided during operation. If the battery is low,* BAT *will appear in the status window. Please refer to Page 51 for a more complete description of the low battery indicators.*

Status Window When Scanning Begins

Once start-up is complete and the **King of Hearts Express AF** recorder begins to scan the patient's ECG activity, it will indicate scanning with a double beep. A new display will appear in the status window.



This flashing symbol indicates that the **King of Hearts Express AF** recorder has started to scan the patient's ECG activity.

The number of events available to be recorded with current programmed settings.

If the heart rate display has been programmed On, the current heart rate appears here.

RECORD AN ECG

While the **King of Hearts Express AF** recorder is scanning the patient's ECG, it is placing the data in an electronic memory loop (memory differs from model to model). New ECG activity replaces oldest ECG activity.

Your patient should use the following procedure as soon as symptoms occur:

- ❖ Press and release the **Record** button.
- ❖ Relax and remain still.

The **King of Hearts Express AF** recorder will capture the ongoing ECG as well as the previous ECG segment from the memory loop (the length of the **bE**fore-event and **AF**ter-event segments that have been programmed).

Automatic Recording

If automatic triggering has been programmed **On**, the recorder may record an ECG when the heart rate is beyond preset tachycardia or bradycardia limits, or when certain atrial fibrillation rhythms are detected. Whether auto triggering is **On** or **Off**, the patient may record an ECG at any time by pressing the **Record** button.

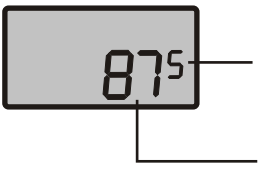
If the event alert (bP) parameter is programmed On, each event automatically recorded by the device based on either the AFIB or heart-rate trigger, will be followed by a beep to inform the user that an auto-triggered event is stored in memory. The beep will repeat once approximately every minute, until the user transmits the event, or cycles power to the device; i.e. by removing and re-plugging the ECG cable jack. If the device subsequently records another auto-triggered event, the beep sequence will restart. **The event alert feature is On/Off programmable via the bP parameter**.

Display and Tone

During ECG recording and storing, the **Record** symbol stops flashing. If the speaker (**SP**) has been programmed **On**, the patient will hear a tone, pulsing rhythmically with the detected heartbeat (not applicable for automatically recorded events). If the **SP**eaker has been programmed **OFF**, the recorder will record silently.

If the heart rate display has been programmed **On**, the patient's heart rate will appear in the status window.

At any given time, the number of events remaining can be observed in the status window while the recorder is scanning.



When recording is completed, if there is sufficient memory to record another event, the **King of Hearts Express AF** recorder emits a single beep and then after a pause, a double beep (silent following auto-recording) and automatically restarts normal scanning mode. The number of events will decrease by one. If the memory is full, an F will appear on the display.

Full Memory

When the memory is full, the recorder will emit a series of five single beeps every three minutes. The beeps may be silenced by removing the lead set jack to stop scanning.

Number of Recorded Events

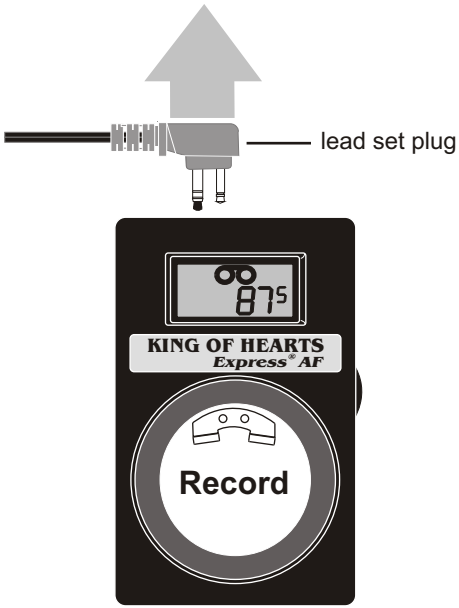
The actual number of recorded events depends on the programmed duration of the recorded segments.

TURN OFF SCANNING MODE

It is necessary to turn off scanning mode:

- ❖ before transmitting the stored ECGs over the telephone
- ❖ to silence the “memory full” or “low battery” indicators
- ❖ to silence the “auto-triggered event reminder”
- ❖ before bathing or showering
- ❖ before changing the batteries
- ❖ before programming
- ❖ when not in use

To turn off scanning mode, remove the lead set plug from the recorder jack. The **King of Hearts Express AF** recorder will beep once, then turn off.



SEND RECORDED DATA

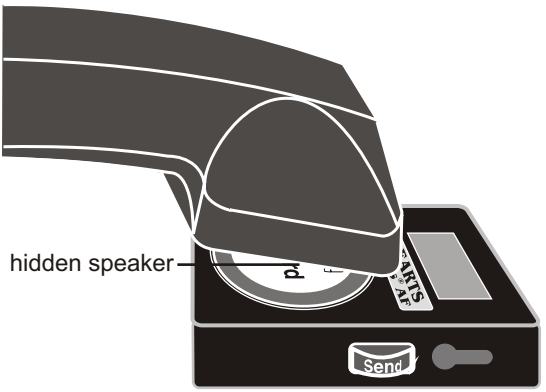
The patient may transmit the stored data after each recording or when the memory is full. Transmissions are sent either to a telephonic ECG receiver in your office or to a receiving service.

You determine the transmission speed by setting the accelerated transmission option **On** or **OFF**. Use the optional accelerated transmission only when sending to a compatible receiver. For all other receivers, use standard transmission.

Note: *If you have a question regarding compatibility of your receiver, call Instromedix Technical Support at 1-800-237-4500.*

All ECGs are sent in sequential order. See Appendix C for samples of ECG strips.

Note: *The telephone used for data transmission must have a handset which will rest reasonably flat over the face of the recorder. Some telephones may not be suitable for use, such as telephones that disconnect when placed on a flat surface.*



To Send Recorded Data

- Unplug the lead set from the jack.
- Place the **King of Hearts Express AF** recorder face up on a flat surface near a telephone.
- Call the receiving service (the telephone number provided by the physician).
- When instructed by the technician, press and hold the **Send** button until the recorder emits a steady tone. For models with a display, a appears in the status window.
- Release the **Send** button.
- **Quickly** place the mouthpiece of the telephone over the **Record** button.

The **King of Hearts Express AF** recorder then transmits all stored ECG data in the order in which it was recorded.

Total transmission time depends on the amount of data stored and the transmission speed. For example: using accelerated transmission, 600 seconds or 10 minutes of recorded ECG will take slightly over 3 minutes to transmit. Using standard transmission, 10 minutes of data will take approximately 10 minutes to transmit.

Audible Signals During Transmission

The patient should hear the following sequence of tones if accelerated transmission (ATP method) and **Id** transmission are both set to **On.**

- When the **Send** button is pressed and held, the recorder will emit a beep, then a steady tone. The symbol will appear in the status window.
- After approximately five seconds, the recorder will emit three clicks, indicating the start of ATP method mode.
- The recorder will then emit three static-like bursts, which is the recorder **Id** being transmitted.
- When all the data has been sent, the recorder will emit a series of three clicks indicating that accelerated data transmission has been completed.

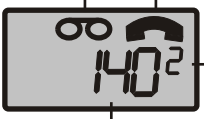
If accelerated transmission and **Id** transmission are both **OFF**, or for models which do not have ATP method or **Id** features:

- When the **Send** button is pressed and held, the recorder will emit a beep, then a steady tone. The symbol will appear in the status window (for models with display).
- After approximately five seconds, the recorder will emit a single beep, followed by the ECG.
- When all the data has been sent, the recorder will emit a single beep, indicating that transmission is complete.

Note: *If the recorder transmits using accelerated transmission (ATP method) and you do not have an ATP method compatible receiver, you will receive a time and amplitude distorted ECG, preceded by a noise burst. Retrieve the recorder and reprogram for standard transmission speed. See p.29 for instructions on turning ATP method on or off.*

Display During Transmission

When the tone stops and the status window is blank, the transmission is complete.



The record symbol appears during initial transmission. The record symbol will not appear during subsequent transmissions.

The telephone symbol indicates that transmission is in progress.

The number of recorded events remaining to be transmitted.

The recorded heart rate currently being transmitted will appear only if the heart rate display has been programmed **On**.

Transmission Can Be Interrupted

The transmission can be interrupted at any time by pressing and holding the **Send** button until the tone stops. When the **Send** button is pressed again, the transmission starts at the beginning.

Transmission Can Be Repeated

A transmission can be repeated as many times as necessary, **until the lead set plug is reinserted into the recorder**.

Transmission may need to be repeated because of a bad recording. Ask the patient to record and transmit another ECG. If this does not correct the problem, retrieve the recorder from the patient and call Instromedix®.

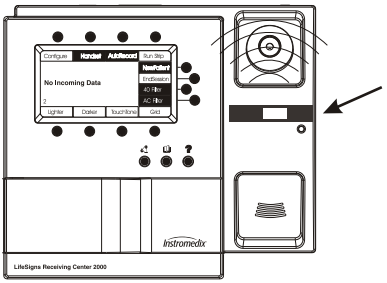
Note: *A 0.5mV, 300mSec square wave pattern at the beginning of a transmission indicates that the scanning memory was not full before the recording was started. This is not a problem condition. See Appendix C for samples of both types of square waves. Square waves with amplitudes of 2mV or higher indicate that the inputs have been overloaded. If this happens, ask the patient to record and transmit another ECG. If this does not correct the problem, retrieve the recorder from the patient and call Instromedix®.*

IN-OFFICE DOWNLOADING

Download patient data in your office by acoustical transfer. You or your staff will use a similar procedure to receive and process the data as a transtelephonic transmission; only the means of connection differs.

Unlike the patient, who transmits the audible signal into his or her telephone, you must manually direct the audible signal into your ECG receiver. In order to do this, you will need either an acoustic coupler attached to the receiver or a receiver that is equipped with a built-in acoustic coupler.

- ❖ Unplug the lead set from the jack.
- ❖ Place the **King of Hearts Express AF** recorder on its side facing the acoustic coupler, as shown below. Make sure the **Send** button faces up.
- ❖ Leave the recorder in this position until the audible signal stops.
- ❖ Prepare the receiver to record the ECG data via the acoustic coupler. Refer to the instruction manual for your receiver.
- ❖ Play back the recording as instructed on Pages 15-18 of this manual.
- ❖ Operate the appropriate controls on the receiver to complete and save the received transmission.



Stand the recorder on its side, facing the acoustic coupler.

ERASE MEMORY

The ECG data will be held in memory UNTIL all recordings have been transmitted and scanning has been restarted. When the lead set is reinserted into the jack, the memory is automatically erased.

The recorded ECGs are automatically erased ONLY under the following conditions:

1. All recordings have been completely transmitted.
2. The lead set plug is reinserted into the recorder to start scanning.

The memory will otherwise remain intact and any new recordings will be added to those already stored (if memory is available).

PROGRAMMING OPTIONS

Programming options allow you to program the **King of Hearts Express AF** recorder to suit the patient's condition and according to your own preferences. These options are summarized below for each model. Default settings are also shown.

KING OF HEARTS EXPRESS AF RECORDER				
OPTION CODE	**OPTION DESCRIPTION**	**AVAILABLE SETTINGS**	**Factory DEFAULT SETTING d1**	**Factory DEFAULT SETTING d2**
d1	Quick select program option for factory defaults.	**On** or **OFF**	**On**	**OFF**
d2	Quick select program option for a second set of defaults.	**On** or **OFF**	**OFF**	**On**
bE	Number of seconds of pre-event memory captured (ECG **bE**fore **Record** is pressed).	5-600 seconds (five second increments)	45	60
AF	Number of seconds of post-event memory to be captured (ongoing ECG **AF**ter **Record** is pressed).	0-595 seconds (five second increments)	15	30
nE	Maximum number of events that can be stored.	60 max limited by 10 seconds minimum **bE**+**AF**, can be reduced to 1 in decrements of 1	10	4
SP	**SP**eaker emits an audible tone/heartbeat during recording. Option code is displayed in the status window.	**On** or **OFF**	**On**	**OFF**
rd	Heart rate will be displayed in the status window.	**On** or **OFF**	**On**	**On**

PROGRAMMING OPTIONS, CONTINUED

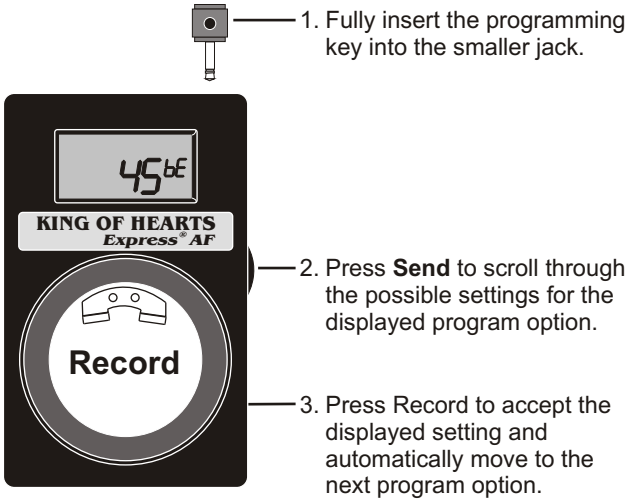
KING OF HEARTS EXPRESS AF RECORDER (Con't)				
OPTION CODE	**OPTION DESCRIPTION**	**AVAILABLE SETTINGS**	**Factory DEFAULT SETTING d1**	**Factory DEFAULT SETTING d2**
Fb	Atrial fibrillation trigger.	**On** or **OFF**	**OFF**	**On**
Ad	Turns automatic rate trigger **On** or **OFF**.	**On** or **OFF**	**OFF**	**On**
dH	Set minimum heart rate for tachycardia detection when auto trigger is on.	Range = 120-250 in steps of 10	200	150
dL	Set maximum heart rate for bradycardia detection when auto trigger is on.	Range = 30-65 in steps of 5	30	30
bP	Auto trigger recorded event alert.	**On** or **OFF**	**OFF**	**On**
nA	Number of events that may be recorded by the automatic rate trigger.	Range = 0 to value set for **nE**-1	1	2
AP	Turns accelerated transmission protocol **On**.	**On** or **OFF**	**OFF**	**On**
nH	First four digits of recorder Identification (LRC™ 2000 receiver required).	Display only; cannot be modified	0000	0000
nL	Last four digits of recorder Identification (LRC™ 2000 receiver required).	Display only; cannot be modified	0000	0000
Id	Recorder Identification number sent before each transmitted event (LRC™ 2000 receiver required).	**On** or **OFF**	**On**	**On**

Factory Programming

Factory defaults are shown on the previous pages.

CAUTION: When a **bE**fore- or **AF**ter-event length is changed, the memory is erased and any stored data is lost.

TO PROGRAM KING OF HEARTS EXPRESS AF RECORDER


45bE
KING OF HEARTS
Express® AF
Record
1. Fully insert the programming key into the smaller jack.
2. Press **Send** to scroll through the possible settings for the displayed program option.
3. Press Record to accept the displayed setting and automatically move to the next program option.

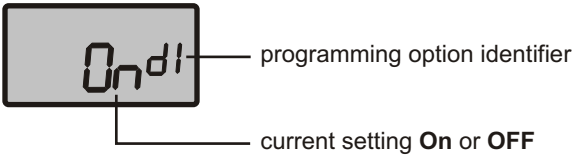
PROGRAM PROCEDURES

With the lead set plug removed from the jack:

To Enter Program Mode

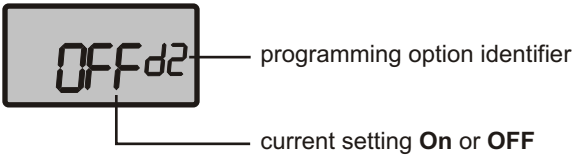
Fully insert the programming key into the smaller of the two holes on the top end of the recorder. The recorder will display the first program option and the current value.

To Set/Restore Factory Default Settings



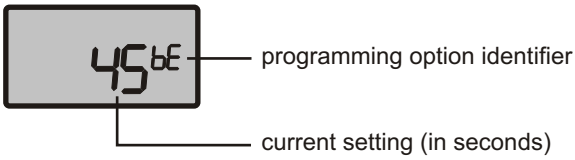
- ❖ Press the **Send** button to toggle between **On** and **OFF**.
- ❖ Press the **Record** button to accept the displayed setting and advance to the next program option.

To Set/Restore a Second Set of Default Settings



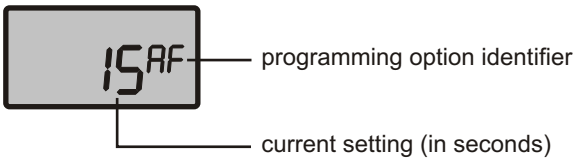
- ❖ Press the **Send** button to toggle between **On** and **OFF**.
- ❖ Press the **Record** button to accept the displayed setting and advance to the next program option.

To Set Before-Event Interval



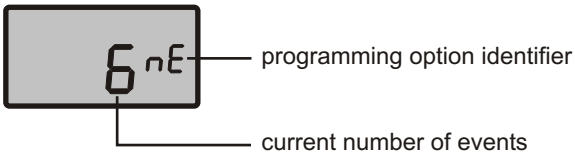
- Press the **Send** button to scroll through the **bE**fore-event time settings until the desired value is displayed. (Repeatedly pressing the **Send** button advances the displayed time by five second increments. Press and hold the Send button to rapidly advance.)
- Press the **Record** button to accept the displayed time setting and to advance to the next program option.

To Set After-Event Interval



- Press the **Send** button to scroll through the **AF**ter-event time settings until the desired value is displayed. (Repeatedly pressing the **Send** button advances the displayed time by five second increments. Press and hold the **Send** button to rapidly advance.)
- Press the **Record** button to accept the displayed **AF**ter-event setting and to advance to the next program option.

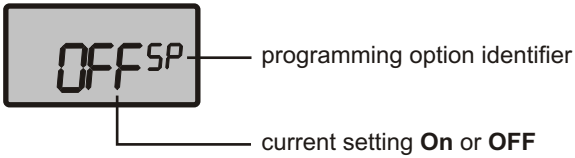
To Limit Maximum Number of Events



You may limit the maximum number of events that a patient may record by adjusting this setting.

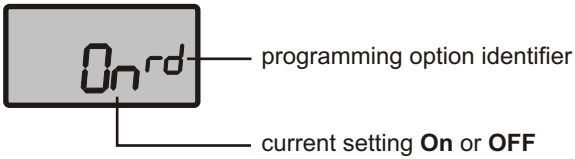
- ❖ Press the **Send** button to set the number of events to be recorded.
- ❖ Press the **Record** button to accept the setting and to advance to the next program option.

To Turn Speaker On/OFF



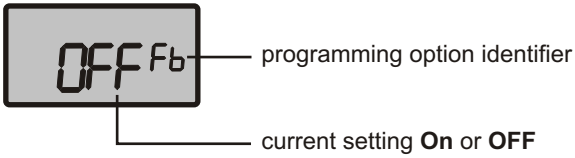
- ❖ Press the **Send** button to toggle between **On** and **OFF**.
- ❖ Press the **Record** button to accept the setting and to advance to the next program option.

To Turn Heart Rate Display On/OFF



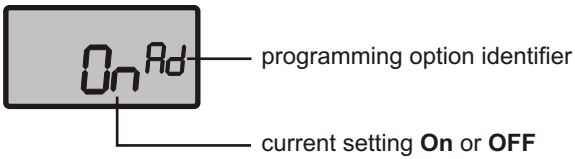
- ❖ Press the **Send** button to toggle between **On** and **OFF**.
- ❖ Press the **Record** button to accept the displayed setting and to advance to the next program option.

To Turn Atrial Fibrillation Trigger On/OFF



- Press the **Send** button to toggle between **On** and **OFF**.
- Press the **Record** button to accept the displayed setting and to advance to the next program option.

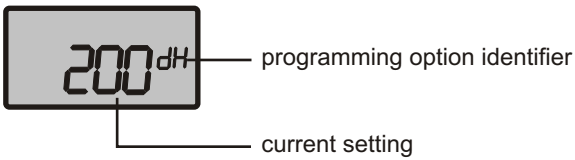
To Turn Automatic Rate Trigger On/OFF



- Press the **Send** button to toggle between **On** and **OFF**.
- Press the **Record** button to accept the displayed setting and to advance to the next program option.

To Set Minimum Heart Rate for Tachycardia Detection

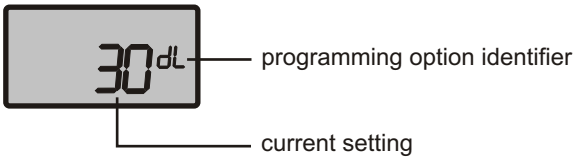
> ***Note:*** *If the Automatic Rate Trigger is set to OFF this program setting is unavailable.*



- Press the **Send** button to scroll through the available settings. Set to highest available number to effectively disable Tachycardia detection only.
- Press the **Record** button to accept the displayed setting and to advance to the next program option.

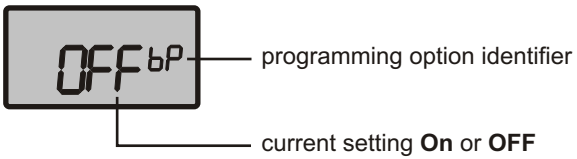
To Set Maximum Heart Rate for Bradycardia Detection

> ***Note:*** *If the Automatic Rate Trigger is set to OFF this program setting is unavailable.*



- Press the **Send** button to scroll through the available settings. Set to lowest available number to effectively disable Bradycardia detection only.
- Press the **Record** button to accept the displayed setting and to advance to the next program option.

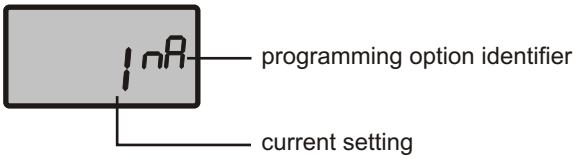
To Turn Auto Recorded Event Alert On/OFF



- Press the **Send** button to scroll through the available settings.
- Press the **Record** button to accept the displayed setting and to advance to the next program option.

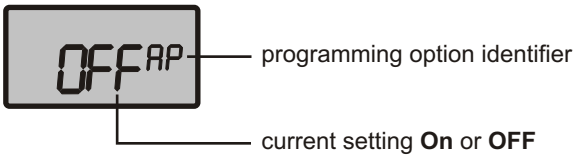
To Set Maximum Number of Automatically Triggered Events

> ***Note:*** *This program setting is not available if **Ad** and **Fb** are set to **OFF**.*



- ❖ Press the **Send** button to scroll through the available settings.
- ❖ Press the **Record** button to accept the displayed setting and to advance to the next program option.

To Turn Accelerated Transmission Protocol On/OFF



The **King of Hearts Express AF** recorder offers the option of transmitting its ECG data in standard mode, which is suitable for a wide range of receivers, or accelerated mode. Use the optional accelerated transmission only when sending to a compatible receiver. For all other receivers, use standard transmission.

> ***Note:*** *If you have a question regarding compatibility of your receiver, call Instromedix Technical Support at 1-800-237-4500.*

- ❖ Press the **Send** button to toggle between **On** and **OFF**.
- ❖ Press the **Record** button to advance to the next program option.

To Display Recorder Number

The **King of Hearts Express AF** recorder displays a device recorder number (device type) which can be logged into the patient's file.

The device recorder number is comprised of 10 digits. It is important to note that the first two digits (73) for identifying the device type (**King of Hearts Express AF** recorder) do not appear in these screens. Displayed here are two sets of 0000 which are preset at the factory. The digits are displayed as shown:

The **nH** indicates that the four highest digits (the first half) of the recorder Identification number (0000) are displayed in the status window.

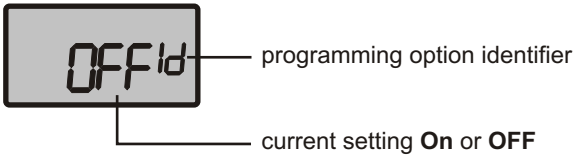
The **nL** indicates that the four lowest digits (the second half) of the recorder Identification number (0000) are displayed in the status window.

- Press the **Record** button to advance from the first half to the second half of the recorder Identification number.
- Press the **Record** button to advance to the next program option.

> ***Note:*** *The complete number begins with two numbers that are not visible on the display above. When the* ***Id*** *number is printed on the ECG strip, a 73 indicates that the recorder is a* ***King of Hearts Express AF*** *recorder.*

> ***Note:*** *The* ***nH*** *and* ***nL*** *values will always be "0000".*

To Turn Recorder Id Number Transmission On/OFF



The **King of Hearts Express AF** recorder offers the option of transmitting the device type identification (**Id**) number. When transmitting to a compatible receiver, the **Id** number 7300000000 will be edge-printed on the ECG strip.

- ❖ Press the **Send** button to toggle between **On** and **Off**.
- ❖ Press the **Record** button to advance to the first program option.

> ***Note:*** *If the recorder Identification number transmission is selected On and the ECG receiver is not recorder Id compatible, the strip will indicate a "noise burst" instead of the recorder Identification number.*

To Leave Programming Mode

- ❖ Remove the programming key. The **King of Hearts Express AF** recorder automatically turns off. You may now activate scanning mode as described on Page 10.

> ***Note:*** *Removing the programming key accepts the displayed setting as well as any other modified program settings.*

- ❖ Store the programming key in a safe place.

PATIENT INSTRUCTION PROCESS

Successful operation of the **King of Hearts Express AF** recorder depends on thorough patient instruction. Instromedix® recommends that you walk through the following steps with each patient.

PREPARE RECORDER

- Prior to the patient's visit, check battery life and, if necessary, install a fresh set of batteries (see Page 38).
- Verify that the desired **bE**fore- and **AF**ter-event time settings are correct and that the desired **SP**eaker and heart rate display options are selected.

DISCUSS SYMPTOMS YOUR PATIENT MAY EXPERIENCE

Because the **King of Hearts Express AF** recorder is patient activated, you should discuss with the patient the possible symptoms that may be experienced. Discuss when to activate the recorder.

Typical symptoms include:

- syncope
- unexplained chest pain (angina)
- intermittent heart palpitations
- transient dizziness or light-headedness
- episodic nausea
- intermittent shortness of breath or breathlessness

DISCUSS PATIENT HOOKUP (see pages 7-9)

- Determine electrode placement
- Prepare placement sites
- Apply electrodes
- Connect lead wires

PERFORM ELECTRICAL CONFIDENCE CHECK

It is good practice to perform an electrical confidence check each time the **King of Hearts Express AF** recorder is connected to a patient or when a lead wire is reattached to an electrode.

- ❖ Place the recorder in scanning mode (lead set plugged into the recorder's jack).
- ❖ Press and hold **Send**.
- ❖ Verify that the audible tone modulates with the patient's heartbeat. If there is no modulating tone or there is a poor signal, perform the steps listed below in the order shown. Check the results after each step.

If the heart **r**ate **d**isplay has been programmed **On**, the heart rate should appear within 20 seconds after start-up and remain on the display during scanning. This verifies that the **King of Hearts Express AF** recorder is functioning properly and that it is receiving the ECG data.

To Troubleshoot a Poor Signal

1. Verify that the **King of Hearts Express AF** recorder is not operating near a source of electromagnetic interference, such as fluorescent lights, computer monitors or household appliances. Verify the same for the telephonic ECG receiver, if applicable.
2. Reinsert the lead set plug into the jack.
3. Repress the electrodes to the skin. Be sure the snap attachments are secure. Electrodes which do not adhere securely must be replaced.
4. Replace electrodes (reprep the skin area, if necessary). Move the electrodes slightly to the right or left of the original sites.
5. Use a new lead set. Discard the old lead set.

Call Instromedix® at 1-800-237-4500.

EXPLAIN BASIC OPERATION OF RECORDER

- Give the patient a copy of all recorder patient literature and review it together.
- Record an ECG to demonstrate proper operation. If the **SP**eaker is programmed **On**, demonstrate the sound of a good signal. A wildly fluctuating tone indicates interference. The patient should stop all movement in order to eliminate mechanical and body noise in the signal.
- Discuss the messages that appear in the status window and the beep patterns that may be heard when the batteries are low or when the memory is full. Explain the steps to be followed as a result.
- Give the patient the **Patient Diary**. Explain the format and request that the patient complete an entry after recording each ECG.

> ***Note:*** *The **Patient Diary** should contain 1) the phone number of your office or the receiving service to which the ECG data is to be transmitted and 2) your designated transmission schedule, if other than when the memory is full. Additional diaries and patient guides are available through Instromedix®.*

- Show the patient how to contact your office or receiving service.
- Familiarize the patient with the routine questions that may be asked.
- Show the patient how to Send the data and restart scanning mode.

It is recommended that the patient repeat the steps of operation while you observe.

DISCUSS WEARING THE KING OF HEARTS EXPRESS® AF RECORDER

- Explain that the **King of Hearts Express AF** recorder must be worn at all times to be useful. If the recorder is taken off and symptoms occur, the event will not be recorded.
- Discuss the patient's daily schedule and activities. Review tasks; such as, bathing and dressing. Discuss proper wearing of the **King of Hearts Express AF** recorder. Answer questions that may arise.

EXPLAIN WHERE TO GO FOR HELP

- Be sure the patient has copies of all patient literature.
- Encourage the patient to call your office if there are any questions.

MAINTENANCE AND SERVICE

The **King of Hearts Express AF** recorder requires no regular maintenance (other than electrode and alkaline battery replacement) and has no user serviceable parts. **Do not** remove the cover or attempt to service any internal components.

Contact Instromedix® for service. If the user wishes to have the recorder serviced by a local service technician, Instromedix® will provide service documentation upon request.

SUPPLIES

The following supplies may be ordered through Instromedix®.

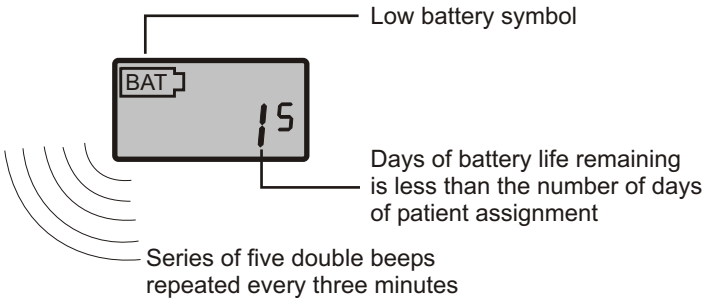
PRODUCT DESCRIPTION	PART NUMBER
Lead-Lok® Pre Gelled Electrodes (case of 50)	010-0027-00
Two Electrode Lead Set	420-0073-00
Belt Clip	665-0226-01
38” Neck Lanyard (cord)	010-0067-00
Programming Key (**King of Hearts Express®** recorder models only)	406-0029-00
1.5V AAA Battery	410-0010-00
Instromedix® Patient Diary	061-0533-00
King of Hearts Express AF “. . . I’m Glad You Asked That!” Patient Guide	061-0693-00
King of Hearts Express AF Quick Reference Card	061-0675-00
King of Hearts Express AF Physician’s Operation Manual	061-0688-00

BATTERIES

The **King of Hearts Express AF** recorders automatically check their own batteries. A fresh set of AAA alkaline batteries typically powers the recorder for seven days. The batteries must be replaced when any of the following occurs:

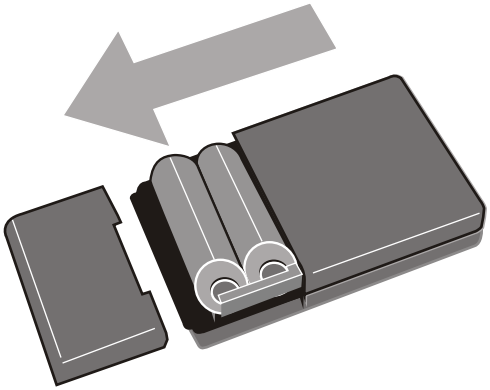
- The low battery symbol BAT appears in the display. This symbol will flash on and off during operation (low battery).
- Low battery indications appear in the ECG chart strip. See Appendix C (low battery).
- The low battery symbol remains on constantly and/or the recorder emits a series of **five double beeps every three minutes**.
- The batteries have discharged to the point that scanning stops or the recorder ceases to function entirely (dead battery).
- The indicated number of days of battery life is less than the number of days of patient assignment. Estimated battery life displays briefly when the lead set is first inserted.

Note: *The displayed days of battery life remaining is only an estimate based on use of fresh Eveready® alkaline batteries. Use of non-standard or old batteries may result in an erroneous value. The* ***King of Hearts Express AF*** *recorder will operate within specifications in a "low battery" condition. It will stop recording when batteries are too low to enable operation within specifications, a "dead battery" condition.*


Low battery symbol
BAT
!5
Days of battery life remaining is less than the number of days of patient assignment
Series of five double beeps repeated every three minutes

To Replace Batteries

- Remove the lead set plug from the jack. Remove the belt clip, if being used. Place the recorder face down on a flat surface.
- Slide the battery compartment door off the back of the recorder.



- Carefully remove the old batteries from the compartment. A blunt, flat object (such as, a coin) may be used to dislodge the batteries.
- Insert two new AAA alkaline batteries. Position the batteries as shown on the floor of the battery compartment.
- Replace the compartment door by sliding it into place. Be sure the door snaps shut.

CAUTION: Use only good quality AAA alkaline batteries; such as, Eveready® E92 batteries (recommended). DO NOT replace just one of the batteries.

PREVENTIVE MAINTENANCE

To ensure that the King of Hearts Express AF recorder continues to perform at maximum capability, and to reduce the possibility of failure, perform the following preventive maintenance tasks on a regular basis.

Mechanical Inspection

Check the lead wires for splits or cracks in the insulation or around the connectors. If the cable shows significant wear or damage it should be replaced.

Cleaning the King of Hearts Express AF Recorder

The case may be wiped clean with a soft cloth dampened in an antibacterial soap and water.

Note: *The* ***King of Hearts Express AF*** *recorder memory is protected by an internal lithium battery, so that any stored data is retained when the main batteries die or are removed for replacement. This lithium battery, which typically lasts 1.3 to 10 years (depending on whether alkaline batteries are kept in the recorder), must be replaced by Instromedix®. To extend the life of this battery, keep AAA batteries in the recorder at all times.*

Note: *If the* ***King of Hearts Express AF*** *recorder is to be stored for a long period (greater than a year), put in fresh AAA batteries before storing and replace the batteries annually.*

HANDLING PRECAUTIONS

The **King of Hearts Express AF** recorder is a valuable medical instrument and must be treated with care.

- ❖ Do not drop the **King of Hearts Express AF** recorder.
- ❖ Do not dangle the **King of Hearts Express AF** recorder by the lead set wires.
- ❖ Do not expose the **King of Hearts Express AF** recorder to excessive dust or to extreme temperatures. In cold weather, wear the recorder under protective clothing.
- ❖ Do not immerse or otherwise allow any liquid to enter the recorder's case. Avoid pouring water or other liquids on the recorder while cleaning.
- ❖ During cleaning, make sure you do not expose the recorder to temperatures in excess of 140°F (60°C).
- ❖ Never use abrasives such as wire wool or metal polish.
- ❖ Do not store the recorder in direct sunlight or near corrosive liquids.

Note: *The* ***King of Hearts Express AF*** *recorder carries an Ingress Protection (IP) rating of 20, which means that the design precludes hazardous access by fingers but is not water tight.*

APPENDIX A

SPECIFICATIONS*

Characteristic	Minimum	Typical	Maximum	Unit
Physical				
Length		3.38		inches
Width		2.13		inches
Thickness		0.7		inches
Weight (with batteries)		100		gm
Environmental				
Operating Temperature	10		40	°C
Storage Temperature	-10		60	°C
Relative Humidity (noncondensing)	10		95	%
Electrical				
Input Impedance (with supplied leads)		3		Mohm
CMR Ratio (at 60Hz)		60		dB
Common Mode Range (AC + DC)		±0.5		V
Differential Range (ECG input range @ 5Hz				
AC		±2		mV
DC		±250		mV
Baseline Reset Time			1	sec
Bandwidth (+1db –3db ref to 5Hz)	0.05		40	Hz
Resolution (calculated)		15.6		µV
Elapsed Timer Resolution	1			sec
Elapsed Timer Accuracy		300		sec/mo
Heart Rate Range	28		255	BPM
Heart Rate Accuracy (averaged over four beats)		±1		BPM
Telemetry Specifications				
Transmission Test Condition: FM modulated, ECG, FSK data, Standard and ATP mode				
Center Frequency	1850	1900	1950	Hz
Deviation (modulated with 1 mV p-p 5Hz)	90	100	110	Hz/mV
FSK0	1850	1900	1950	Hz
FSK1	2400	2450	2590	Hz

Characteristic	Minimum	Typical	Maximum	Unit
Battery Specifications				
Alkaline Battery				
(2 AAA Eveready® E92 batteries, or equivalent)			3.0	V
Life			7	days
(Fresh batteries, loop recording, transmit once a day)				
Lithium Battery				
(not user replaceable)		3.6		V
Life (with alkaline batteries in)			10	years
Life (with alkaline batteries out)	1.3	1.5		years
Memory Specifications				
Memory Hold Time			128	days
Elapsed Time (since first recording)			31	days
Recording Period – depends on model				
(sampling rate of 218Hz)	120		600	sec
Auto Trigger				
Bradycardia trigger range	30		65	BPM
Tachycardia trigger range	120		250	BPM
Telephone System Minimum Performance Parameters				
30dB signal to noise ratio				
-15dBm signal power (within a frequency range of 1,000 to 3,000 Hz)				

Characteristic	Typical	Unit
QRS Detection		
AHA, MIT & NST databases combined results.		
Positive Predictivity	97.3	%
QRS Sensitivity	91.4	%

Note: *No "Low battery" or no "Dead battery" indication and no recorder operation are indications of a fully depleted battery or a missing battery.*

Recorder Classification

Type 3 per the AAMI EC38-94 standard.

* Specification change privileges reserved.

APPENDIX B

SYMBOLS

Type BF

Refer to accompanying documentation

CE 0086 CE MARK (European Designation)

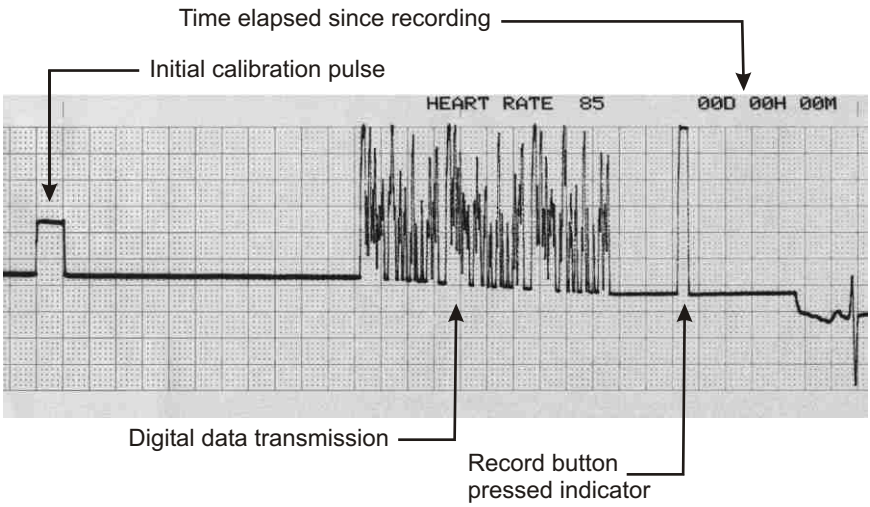
APPENDIX C

TRANSMITTED DATA

ECG recordings transmitted from the **King of Hearts Express AF** cardiac event recorder contain distinctive waveforms, which serve a variety of purposes. Some of these waveforms act as markers to help you interpret the resulting ECG strips, while other waveforms identify certain operating states of the recorder and do not directly influence a successfully recorded and transmitted ECG. Recordings may also contain abnormal waveforms due to physical movement or electrical noise. Please review the chart strips on the following pages.

Note: *If the recorder transmits using accelerated transmission (ATP method) and you do not have an ATP method compatible receiver, you will receive a time and amplitude distorted ECG, preceded by a noise burst. Retrieve the recorder and reprogram for standard transmission speed.*

Transmitting to a Standard LRC™ Receiver



INITIAL CALIBRATION PULSE: A 1.0mV, 200mSec pulse marks the beginning of each transmitted ECG.

DIGITAL DATA TRANSMISSION: When transmitting to a standard LRC™ receiver, if the recorder **Id** transmission is set **On**, the digital data will appear as a noise burst and will not print on the strip in alphanumberic characters.

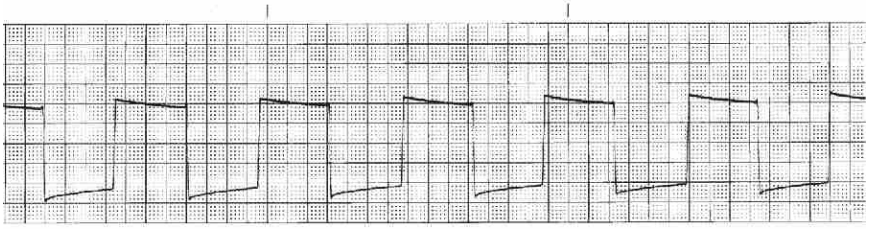
ELAPSED TIME: This mark indicates the length of time between recording and transmission.

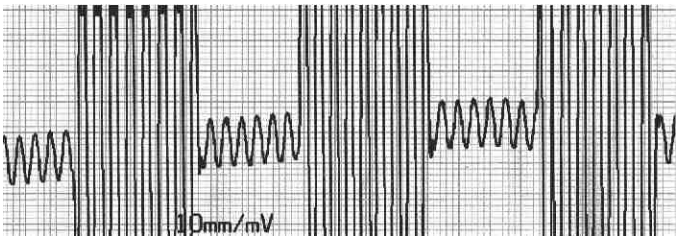
RECORD BUTTON PRESSED INDICATOR: A 5mV, 100mSec spike marks the point that the patient initiated the event recording. It separates **bE**fore-event waveforms (history) from **AF**ter-event waveforms.

DO NOT USE ACCELERATED TRANSMISSION WHEN SENDING TO STANDARD LRC™ RECEIVER.

Overload Waveform

Large square waves with amplitudes of 2mV or higher indicate that the inputs of the **King of Hearts Express AF** recorder may have been overloaded. If this happens, ask the patient to record and transmit another ECG. If this does not correct the problem, retrieve the recorder from the patient and call Instromedix®.

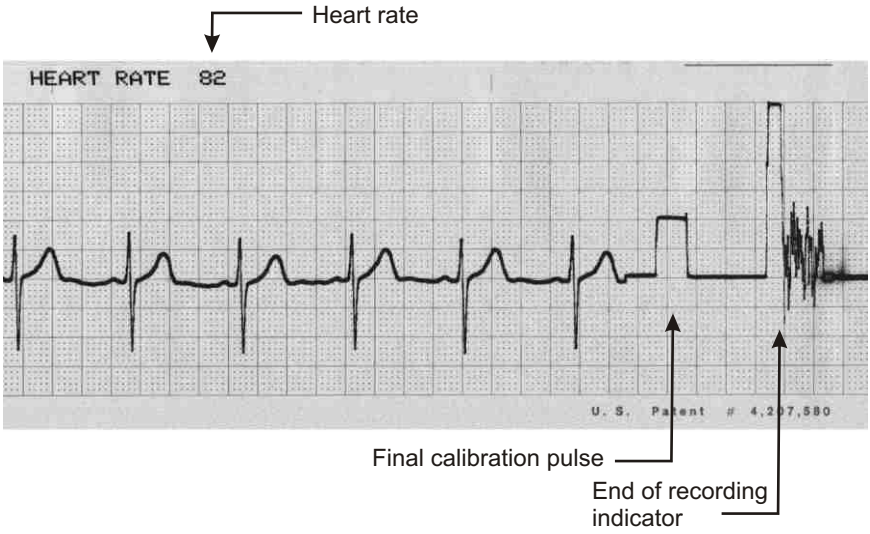




EXAMPLES OF OVERLOAD WAVEFORM

Note: *The waveform will appear as either of the two examples above, depending on the frequency and amplitude of the input signal.*

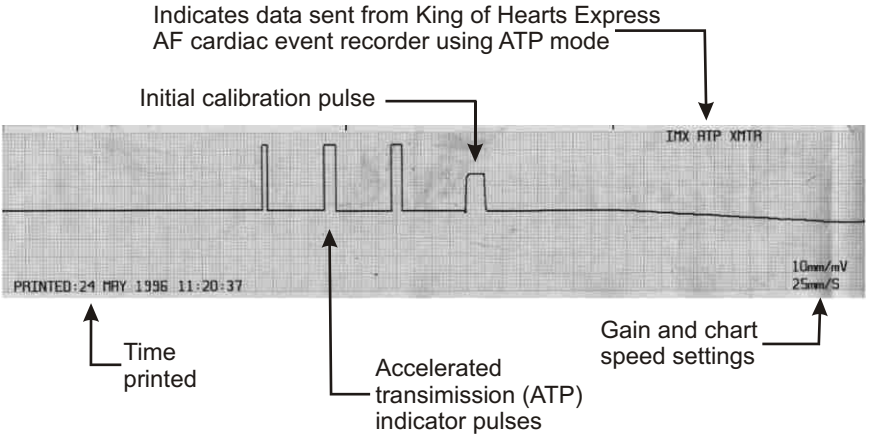
Transmitting to a Standard LRC™ Receiver

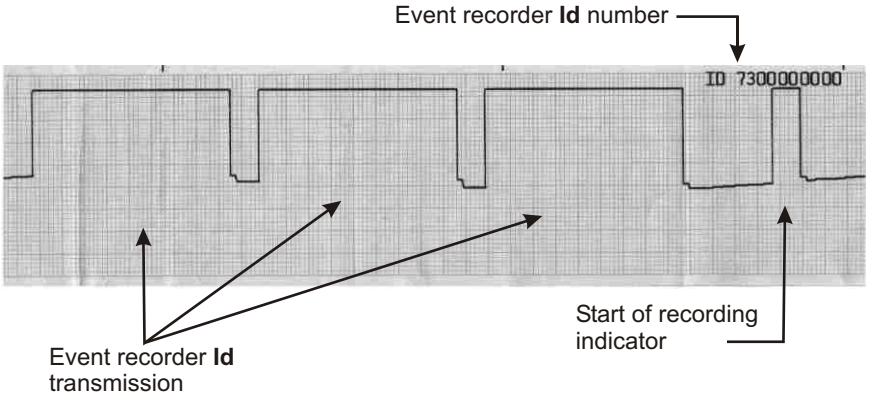


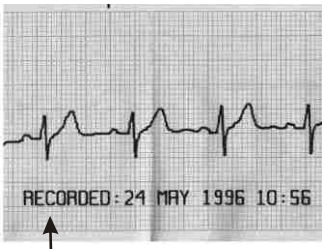
HEART RATE: The heart rate is averaged and printed every seven seconds. Standard transmission mode is required for proper heart rate.

FINAL CALIBRATION PULSE and END OF RECORDING INDICATOR: These marks show that all ECG data stored in the recorder memory has been transmitted.

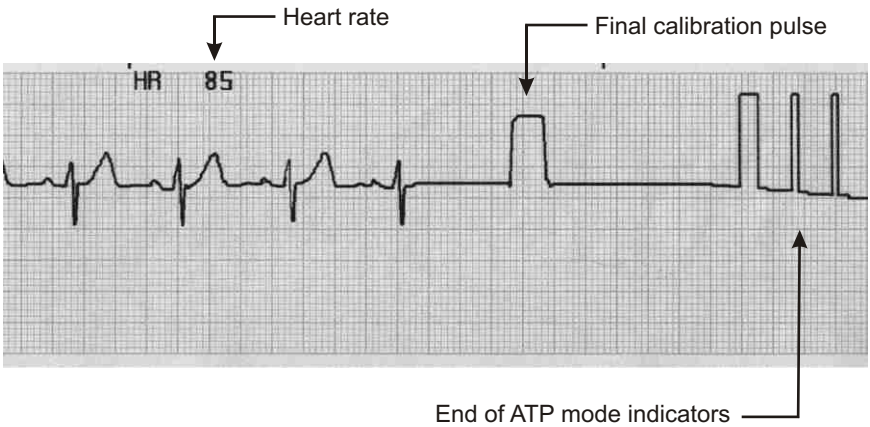
Transmitting to an LRC™ 2000 Receiver


Indicates data sent from King of Hearts Express AF cardiac event recorder using ATP mode
Initial calibration pulse
IMX ATP XMTR
PRINTED:24 MAY 1996 11:20:37
10mm/mV
25mm/S
Time printed
Accelerated transimission (ATP) indicator pulses
Gain and chart speed settings





Transmitting to an LRC™ 2000 Receiver

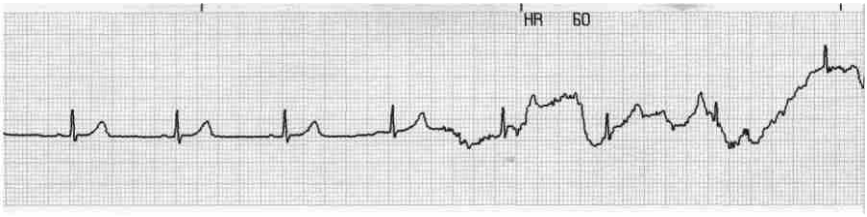


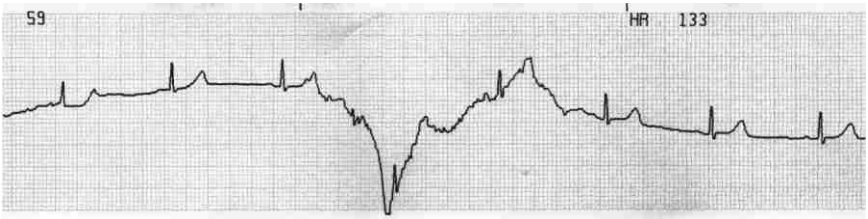
INITIAL CALIBRATION PULSE, RECORD BUTTON PRESSED, HEART RATE and FINAL CALIBRATION PULSE: Same as on previous pages.

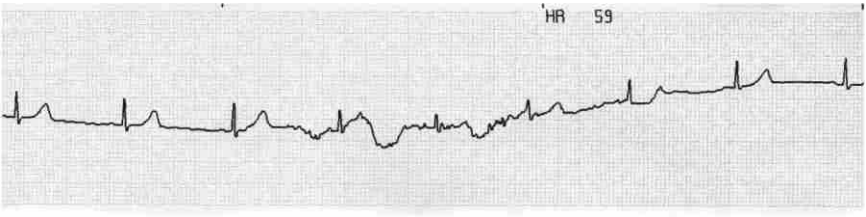
ATP INDICATOR PULSES: These spikes show that the recorder is transmitting in Accelerated Transmission Protocol method at three times the normal speed.

EVENT RECORDER Id TRANSMISSION: If **Id** transmission is set **ON**, the recorder identification number (see page 30) is sent in a data stream and printed as a 10 digit number (7300000000).

> ***Note:*** *If the recorder transmits using accelerated transmission (ATP method) and you do not have an ATP method compatible receiver, you will receive a time and amplitude distorted ECG, preceded by a noise burst. Retrieve the recorder and reprogram for standard transmission speed.*

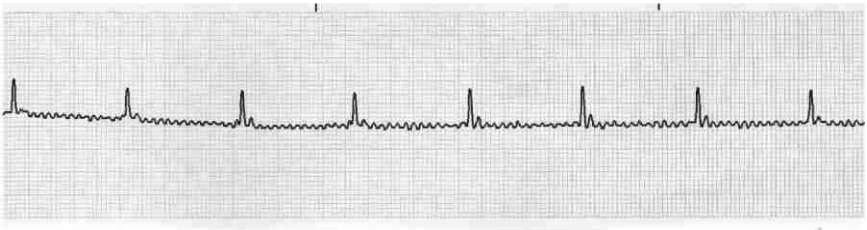






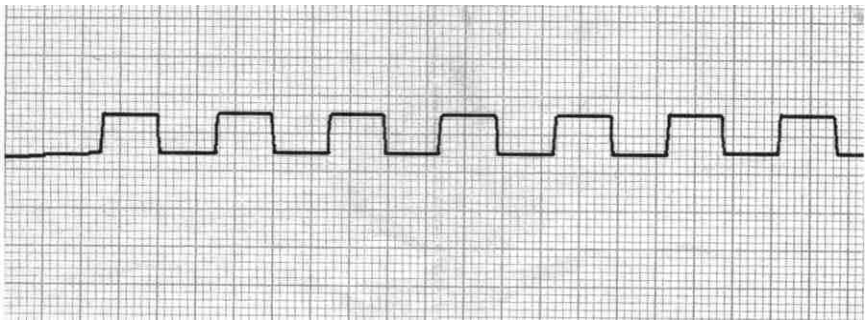
Motion Artifact

Motion artifact results when there is a poor connection between the patient's skin and the **King of Hearts Express AF** recorder, and the electrode is stressed by physical movement during recording. See "To Troubleshoot a Poor Signal" on Page 33, which describes how to remedy a faulty connection. Additionally, the patient should be advised to remain still and quiet during the recording cycle.



Electrical Noise

Electrical Noise refers to additional electrical signals that distort the ECG. The intruding signals may be generated, for example, by machinery operated in the vicinity of the **King of Hearts Express AF** recorder during transmission, by the telephone, or even by fluorescent lighting at the receiving location. The LifeSigns® Receiving Center and the LRC™ 2000 receivers are each equipped with two filters: LINE (for 50-60Hz power line noise) and 40Hz (for nonspecific noise and artifact). Use of these will minimize the effect of “noise”.



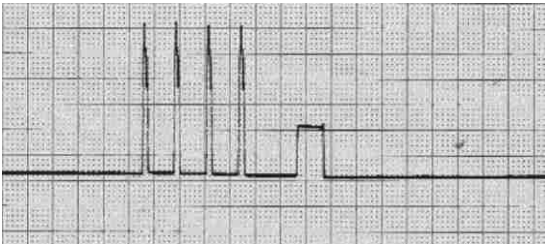
Square Wave A

If the **Record** button is pressed before the **bE**fore-event memory is filled, the unused part of the **bE**fore-event memory is indicated with a 0.5mV, 300mSec square wave. This will occur whenever the time period between events is shorter than the programmed **bE**fore-event time setting.

ECG recordings cannot overlap, so if **Record** is pressed again soon after a recording is made, the second ECG will begin with square waves representing any time period captured in the previous ECG recording.

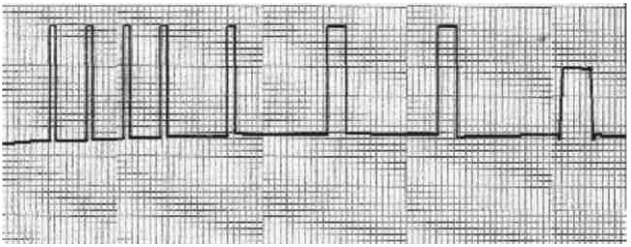
Low Battery Indications

Transmitting to Standard LRC™ Receiver

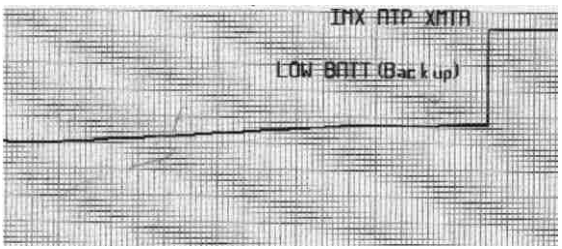


Spikes indicate a low battery condition. Two spikes indicate a low main battery. Four spikes indicate a low backup battery. Six spikes indicate low main and backup batteries.

Transmitting to LRC™ 2000 Receiver



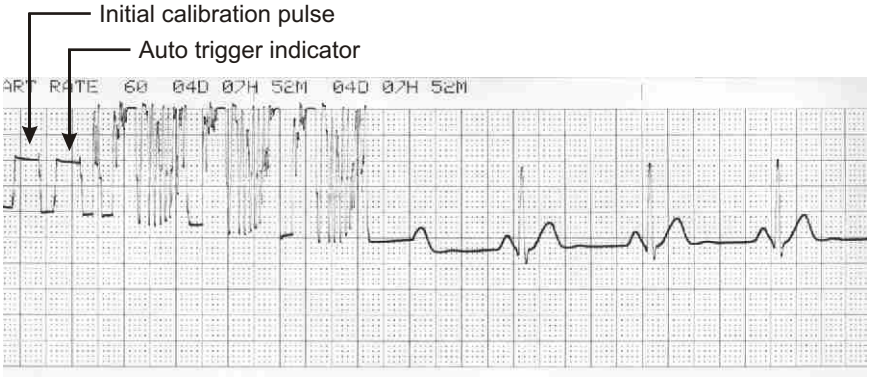
Narrow square waves indicate a low battery condition. Two square waves indicate a low main battery. Four square waves indicate a low backup battery. Six square waves indicate low main and backup batteries.



The LRC™ 2000 receiver prints whether the low battery condition applies to the main, the backup, or both batteries.

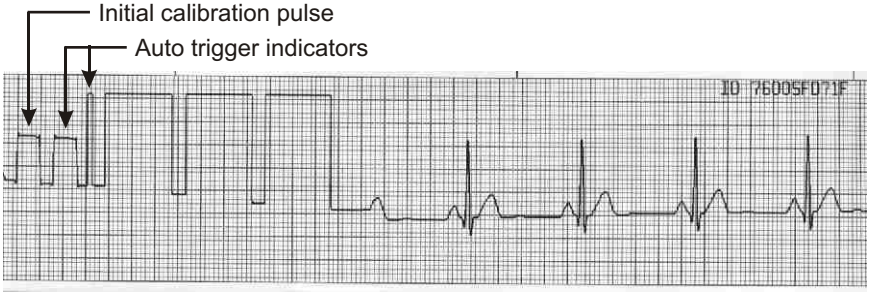
Heart Rate Based Auto Trigger Indications

Transmitting to Standard LRC™ Receiver



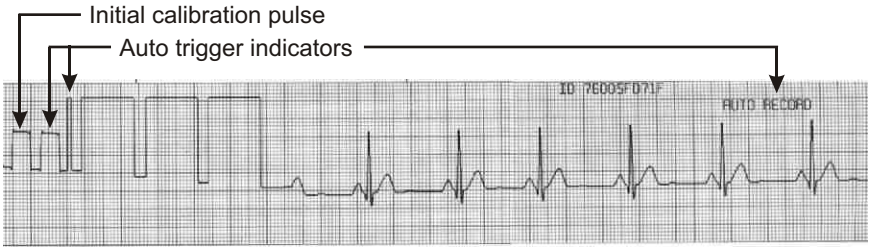
The Standard LRC™ receiver indicates an auto triggered event by printing a 1.0mV, 200mSec pulse immediately following the initial calibration pulse.

Transmitting to LRC™ 2000 Receiver



The LRC™ 2000 receiver indicates an auto triggered event by printing a 1.0mV, 200mSec pulse followed by a narrow square wave, immediately following the initial calibration pulse.

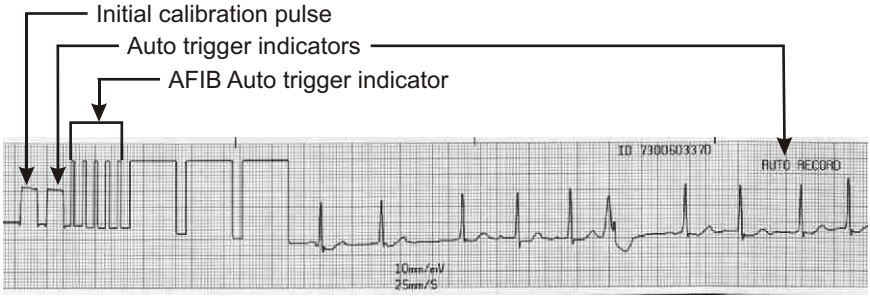
Transmitting to LRC™ 2000ML (Multi-Lead) Receiver



The LRC™ 2000ML receiver follows the same scheme as the LRC™ 2000 receiver and additionally prints a text message identifying the recording.

Atrial Fibrillation Auto Trigger Indication

Transmitting to LRC™ 2000ML (Multi-Lead) Receiver



The LRC™ 2000ML receiver indicates an auto triggered AFIB event by printing a 1.0mV, 200mSec pulse followed by five narrow square waves, immediately after the initial calibration pulse.

APPENDIX D

HEART RATE BASED AUTO TRIGGERING

Per definitions published in the AAMI standard EC38-94, the **King of Hearts Express AF** recorder does not perform analysis.

The heart rate detector in the **King of Hearts Express AF** recorder averages three valid and consecutive QRS intervals to calculate a heart rate reading. Three of these heart rate readings (each calculated from 3 QRS intervals) are processed to detect Bradycardia and Tachycardia and to trigger the recorder to record an event; therefore, for detection, the Tachycardia or the Bradycardia event must be sustained for at least three heart rate readings or 10 heart beats. Events shorter than 10 heart beats will be ignored and will not trigger the recorder.

The Tachycardia/Bradycardia algorithm detects an event and initiates an automatic recording if the following condition is satisfied:

If three heart rate readings in a row exceed the programmed limits of Tachycardia or Bradycardia. These limits are programmed using the programming key and are set to default values of 200bpm and 30bpm for Tachycardia and Bradycardia, respectively. The range for Tachycardia trigger is 120-250 at 10bpm intervals. The range for Bradycardia trigger is 30-65 at 5bpm intervals.

The heart rate detector algorithm was tested on the AHA, MIT, and NST ECG databases. The AHA and MIT databases are real ECGs. The NST database has added artificial noise. The results show that the **King of Hearts Express AF** recorder performs better when noise levels are low; therefore, to avoid triggering on noise, good skin preparation techniques and high quality electrodes must be used.

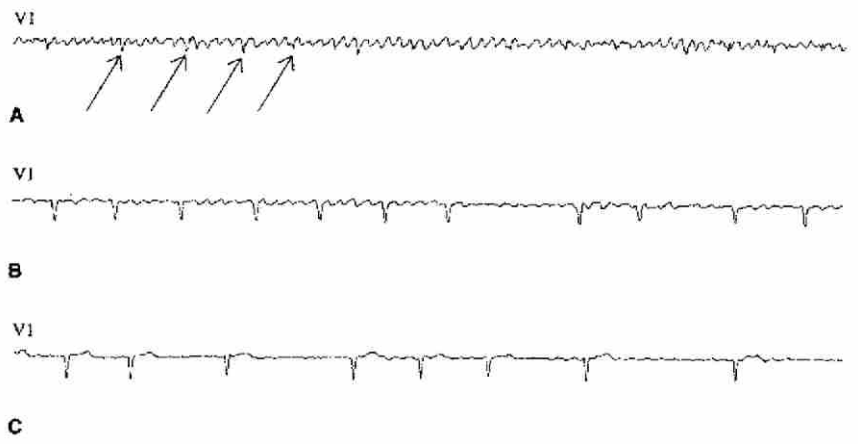
After an event is detected and automatically recorded, the algorithm waits for the triggering condition to be removed (heart rate to return to normal) before it will start looking for more events.

The recorder calculates heart rate by measuring the interval between four consecutive heart beats. Occasionally, due to noise or weak signal strength, the recorder will register a “false positive” or a “false negative” heart beat. When this happens, the calculated heart rate will likely be 33% higher or lower than the true heart rate.

APPENDIX E

ATRIAL FIBRILLATION (AFIB) DETECTION ALGORITHM AND PERFORMANCE STATISTICS

Atrial Fibrillation (AFIB) is a potentially life threatening irregular cardiac rhythm. Atrial Fibrillation occurs when the atria fire at a very rapid rate (up to 600 beats per minute), Fortunately, only some of these impulses make it through the AV node to depolarize the ventricles resulting in an irregular ventricular rate.



The **King of Hearts Express AF** recorder uses a proprietary algorithm for detection of AFIB condition in the acquired ECG waveform. The algorithm utilizes an exponential moving-average based calculation of R-R interval variability for each successive QRS detection. Based on this calculation and preset threshold values, AFIB condition is flagged. The algorithm relies on the fact that atrial fibrillation almost always presents an irregularly-irregular ventricular rhythm.

When AFIB condition is detected in the acquired ECG waveform, the device will automatically record and store the ECG based on BEFORE+AFTER memory setting. The AFIB auto-trigger will re-enable for next AFIB recording after the algorithm detects reversal or end of the AFIB condition.

Database Test Results – (Including All Events)

Database	Statistics	ESe	E+P	DSe	D+P
MIT-BIH	Gross	81	72	74	54
	Average	88	70	81	55
MIT-AF	Gross	81	54	75	59
	Average	79	78	80	71

Database Test Results – (Ignoring events less than 30 seconds)

Database	Statistics	ESe	E+P	DSe	D+P
MIT-BIH	Gross	93	80	82	53
	Average	94	76	85	60
MIT-AF	Gross	94	78	83	82
	Average	90	78	79	70

ESe = episode sensitivity, E+P = episode positive predictivity,
DSe = duration sensitivity, D+P = duration positive predictivity

Note: *Although the device AFIB detection algorithm is very sophisticated, there is no guarantee that the device will catch all episodes of AFIB condition, nor there is any guarantee that the transition to AFIB condition will be successfully recorded in all auto-triggered events.*

APPENDIX F

LIMITED WARRANTY

This Instromedix® (“Instromedix”) product is warrantied against defective material and workmanship (excluding batteries and connecting cables) for two years following delivery of this product to the original purchaser.

If this product or any part thereof, in the judgement of Instromedix, is proven to be defective in material or workmanship within two years from date of original purchase, such defects will be repaired or replaced (at Instromedix’s option) free of charge for parts or labor.

This warranty does not apply to any product which has been damaged by accident or which has been misused, abused, altered or repaired by anyone other than Instromedix or its representatives.

Instromedix shall not be liable to any person for any direct or consequential damages resulting from or caused by any defect, failure or malfunction of this product.

This warranty is in lieu of all other warranties expressed or implied, including any implied warranty of merchantability or fitness for a particular purpose, and no person is authorized to assume for Instromedix any other liability in connection with the sale of this product.

To obtain factory service, this product should be shipped prepaid to Instromedix at the address shown below. In–warranty product will be returned postage prepaid.

In the USA contact:
Instromedix
A Card Guard Company
6779 Mesa Ridge Road, Suite 200
San Diego, California 92121-2996